## REMARKS

The specification has been amended by adding the abstract which appeared on the cover page of the published PCT pamphlet (and at the end of the priority application) as a new page at the end of the specification.

The Examiner's presumption that the subject matter of the claims was commonly owned at all relevant times is correct.

Claim 1 was provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending application no. 10/596,434. While not agreeing that this is a double-patenting situation, applicants include a terminal disclaimer *vis-à-vis* the co-pending application to obviate this rejection. The terminal disclaimer is signed by the attorney of record. In the event the conflicting claims do not issue in the patent, please cancel this terminal disclaimer. Please charge the assignee's deposit account no. 14-1270 for the fee required by 37 CFR 1.20(d).

Claims 1-10 were rejected under 35 U.S.C. §103(a) as unpatentable over US published application no. 2002/0018588 (Kusch) in view of US Pat. 6,996,430 (Gilboa et al.). This ground of rejection is respectfully traversed. Claim 1 describes a medical system comprising a medical instrument to be guided in a patient body, X-Ray acquisition means for acquiring a two-dimensional X-ray image comprising a projection of the medical instrument in accordance with a geometry of the X-Ray acquisition means, ultrasound acquisition means for acquiring a three-dimensional ultrasound data set of the medical instrument using an ultrasound probe, means for localizing the ultrasound probe within a referential of the X-ray acquisition means, means for providing a first ultrasound localization of the medical instrument within a referential of the ultrasound acquisition means, means for converting the first ultrasound localization within the referential of the ultrasound acquisition means into a first X-ray localization within the referential of the X-ray acquisition means, using the localization of the ultrasound probe, means for providing a second X-ray localization of the projection of the medical instrument in a referential of the two-dimensional X-ray image, means for mapping the three-dimensional ultrasound data set with the two-dimensional X-ray image in accordance with a transformation, which minimizes a distance between a projection of the first X-ray localization on the two-dimensional X-Ray image in accordance with the geometry of the X-Ray acquisition means and the second X-ray localization, and means for generating and displaying a bi-modal representation of the medical instrument in which the two-dimensional X-ray image and the mapped three-

dimensional ultrasound data set are combined. An implementation of the present invention enables live guidance of a procedure with an invasive medical instrument such as an electrophysiology probe by means of both live x-ray imaging and live 3D ultrasound imaging. The medical instrument is shown in both the 3D ultrasound image and in a 2D X-ray projection image which are converted to the localization of the X-ray acquisition means and displayed in a bi-modal 2D X-ray image and a 3D ultrasound data set. Two localizations of a projection of the medical instrument into a referential coordinate system of the two-dimensional X-ray image are provided in the transformation, which minimizes a distance D between a projection of the first X-ray localization on the 2D X-ray image in accordance with the geometry of the X-ray acquisition and the second localization, which is very simple. See page 10, lines 19-33 of the specification. Such a mapping transformation of 3D ultrasound data and a 2D x-ray image are not shown or suggested in the prior art. Furthermore, an implementation of the present invention only uses 2D x-ray imaging rather than 3D x-ray imaging, using the coordinate system of one of the imaging modalities rather than a separate coordinate system of a navigation system. The combination of these measures, described in Claim 1, make it possible to perform live guidance of an EP procedure.

Kusch is producing fused 3D x-ray and 3D ultrasound images using a C-arm x-ray system, an ultrasound system, and an optical navigation system. To bring the 3D image data sets of the two modalities to a common coordinate system, the x-ray system, the ultrasound scanner 24, and the patient P are tagged with reference elements 6, 7, and 8 of the navigation system. This enables the conversion of all of the image data sets from the imaging systems to a reference coordinate system K. See paragraphs [0027] and [0030]. With both image data sets converted to a common coordinate system, the two 3D image data sets can be fused, or superimposed on one another. See the first sentence of paragraph [0029]. Kusch does not use the coordinate system of the x-ray system as the referential coordinate system as recited in Claim 1. Furthermore, Kusch does not give any thought to imaging invasive instruments. And there is no image data transformation which minimizes a distance D between a projection of the first X-ray localization on the 2D X-ray image in accordance with the geometry of the X-ray acquisition and the second localization as called for by Claim 1. Thus, Kusch fails to show or suggest at least three of the elements of Claim 1.

Gilboa et al. also use a navigation system (locating system 130) to locate an x-ray system, an ultrasound probe, the patient, and a treatment probe 170. To use the locating

system Gilboa et al. attach sensors to each of these objects. It is seen from the Gilboa et al. patent that Gilboa et al. do not use the coordinate system of the x-ray system, but the coordinate system of their locating system and sensors. Gilboa et al. align their image data by manipulating the ultrasound transducer until they get a projection with the desired data, as they illustrate with the projections of Fig. 2a-2f. As they say in col. 9, lines 64-67, by changing the orientation of the ultrasound transducer the shape and location of image elements are significantly changing." The ultrasound image is then projected onto two perpendicular x-ray image planes as described at the top of col. 10. When the probe is navigated, landmarks and points of interest are re-located where desired. Claim 1 does not use probe manipulation, but data mapping of ultrasound and x-ray image data There is no suggestion of minimizing a distance between the projections of two x-ray localizations as called for by Claim 1. Thus, Gilboa et al. fail to provide the three claim elements that are missing from Kusch. It is respectfully submitted that for these reasons the combination of Kusch and Gilboa et al. cannot render Claim 1 and its dependent Claims 2-9 unpatentable.

Claim 10 describes a method of guiding a medical instrument in a patient body, comprising the steps of acquiring a two-dimensional X-ray image using an X-ray acquisition system, the two-dimensional X-ray image comprising a projection of the medical instrument in accordance with a geometry of the X-ray acquisition system, acquiring a three-dimensional ultrasound data set of the medical instrument using the ultrasound probe, localizing the ultrasound probe in a referential of the X-ray acquisition system, providing a first localization of the medical instrument within a referential of the 3D ultrasound data set, converting the first localization within the referential of the 3D ultrasound data set into a first X-Ray localization within the referential of the X-ray acquisition system, providing a second localization of the projection of the medical instrument in a referential of the two-dimensional X-Ray image, mapping the three-dimensional ultrasound data set with the two-dimensional X-ray image in accordance with a transformation, which minimizes a distance between a projection of the first X-Ray localization on the two-dimensional X-Ray image in accordance with the geometry of the X-Ray acquisition means and the second localization, and generating and displaying a bimodal representation of the medical instrument in which both 2D X-ray image and the mapped 3D ultrasound data are combined. As previously mentioned, both Kusch and Gilboa et al. use a coordinate system of an independent navigation system, an optical navigation system 3 for Kusch and a locating system 130 with multiple sensors in Gilboa et al., both of which require extensive calibration before use. Neither patent shows or suggests localizing an ultrasound probe to the coordinate reference

system of an x-ray acquisition system. Furthermore, neither patent suggests mapping two data sets by minimizing a distance between the projections of two x-ray localizations as called for by Claim 10. Neither patent suggests converting a localization of a medical instrument within ultrasound data to a localization in the reference coordinate system of an x-ray acquisition system. For these reasons it is respectfully submitted that Claim 10 is patentable over Kusch and Gilboa et al.

It is noted that the projection line 36 of Fig. 7 mentioned in the second line of page 11 of the specification has the "6" missing. Accordingly a replacement sheet for Fig. 7 is enclosed in which this projection line is correctly identified by the reference number "36". It is respectfully requested that the Examiner approve entry of this replacement sheet drawing.

The optical image guided surgery system of the Buurman patent US 5,902,239 which was made of record but not relied upon has been reviewed and is not believed to affect the patentability of the present claims.

In view of the foregoing disclaimer, amendment and remarks, it is respectfully submitted that the abstract is now properly on a separate page of the specification and that Claims 1-10 are patentable over the combination of the Kusch and Gilboa et al. Accordingly it is respectfully requested that the rejections of Claims 1-10 under 35 U.S.C. §103(a) and provisionally for double patenting be withdrawn.

In light of the foregoing amendment and remarks, it is respectfully submitted that this application is now in condition for allowance. Favorable reconsideration is respectfully requested.

Respectfully submitted,

OLIVIER GERARD ET AL.

By: /W. Brinton Yorks, Jr./
W. Brinton Yorks, Jr.
Reg. No. 28,923

Philips Electronics
22100 Bothell Everett Highway
P.O. Box 3003
Bothell, WA 98041-3003
(425) 487-7152
September 28, 2009